How will CTU Applications be Evaluated?

Tentative Review Plan

Multiple Special Emphasis Panels (SEPs) will review the CTU application by Research Areas

- Vaccine Research and Development
- Translational Research/Drug Development
- Optimization of Clinical Management, including Co-Morbidities
- Microbicides
- Prevention of Mother-to-Child Transmission of HIV
- Prevention of HIV Infection

Tentative Review Plan (continued)

- **The Panel will have expertise in:**
- The appropriate research area(s)
- Coordination and management of large trials
- Conducting and participating in trials
- Multi-center and international
- Resource limited settings
- In country Knowledge

Tentative Review Plan (continued)

- **Discussion and Scoring:**
- The administrative component including the mentoring plan and the foreign component will be discussed
- Each Clinical Research Site will be discussed and scored
- The overall merit of the CTU will be discussed and scored by scientific priority area

Tentative Review Plan (continued)

- **The following will be considered in the overall score:**
  - Administrative component, contributions to Network(s), Community involvement, plans to foster new investigator development, mentoring plan (if applicable), foreign component (if applicable)
  - Contributions of Clinical Research Sites to the relevant scientific area

Standard Review Criteria

1. Significance
2. Approach
3. Innovation
4. Investigators
5. Environment

Significance

- Does this study address an important problem?
- If the aims of the application are achieved, how will scientific knowledge or clinical practice be advanced?
- What will be the effect of these studies on the concepts, methods, technologies, treatments, services, or preventative interventions that drive this field?

Approach

- Are the conceptual or clinical framework, design, methods, and analyses adequately developed, well integrated, well reasoned, and appropriate to the aims of the project?

- Does the applicant acknowledge potential problem areas and consider alternative tactics?

Innovation

- Is the project original and innovative?
  - Does the project challenge existing paradigms or clinical practice; address an innovative hypothesis or critical barrier to progress in the field?
  - Does the project develop or employ novel concepts, approaches, methodologies, tools, or technologies for this area?

Investigators

- Are the investigators appropriately trained and well suited to carry out this work?
- Is the work proposed appropriate to the experience level of the principal investigator and other researchers?
- Does the investigative team bring complementary and integrated expertise to the project?

Environment

- Does the scientific environment in which the work will be done contribute to the probability of success?
- Do the proposed studies benefit from unique features of the scientific environment, or subject populations, or employ useful collaborative arrangements?
- Is there evidence of institutional support?

CTU-specific Implementation of Review Criteria

Administrative Component

1. Principal Investigators' qualifications, time commitment, experience and vision in the design, coordination.

2. Likelihood of success of proposed contributions to each Network and/or high priority research area with which the CTU seeks alignment.

3. Organizational, management, and communication plans within the CTU.

4. Plans to engage local communities
   - Proposed Community Advisory Board(s)
   - Community outreach
   - Community education

5. Participation of new investigators and clinical research staff, especially women and racial/ethnic minorities in the full spectrum of CTU activities.

Clinical Research Sites

1. Participant cohorts for each Network or scientific priority area proposed
   - demography
   - incidence and prevalence of HIV/AIDS

2. Plans to recruit and retain research participants including underrepresented populations
   - ethnic/racial minorities
   - children
   - women
   - intravenous drug users.

3. Plans to protect clinical trial participants from research risks including
   - pregnant women
   - neonates and fetuses
   - children
   - prisoners

Clinical Research Sites (continued)

4. Documented staff ability to manage sufficient numbers of participants
   - recruit, screen, enroll,
   - follow and retain
   - manage required clinical care

5. Adequacy of facilities to manage sufficient numbers of participants

6. Feasibility of plans to develop an effective partnership with the community
   - elicit community support
   - involve the community in all site activities

Clinical Research Sites (continued)

7. Capacity to conduct clinical research
   - personnel
   - data management
   - compliance with regulatory requirements
   - adherence to Network policies and procedures

8. Documented organizational support of clinical research activities.

9. Appropriateness of timelines for submission of data, and regulatory requirements (IRB requirements.)

Mentoring Partnerships

1. Strength and merit of the Mentoring Partnership plan
    - training
    - exchange of scientific expertise and experience
2. Likelihood that plans will contribute to the CTU capability to conduct clinical research within timeframe specified.
3. Mentor(s) qualifications to meet Mentoring Partnership goals and objectives.
4. Appropriateness of Mentor(s) role and stated commitment to meeting Partnership goals and objectives.

Additional Review Criteria

1. Plans for protection of human subjects from research risk

2. Plans for inclusion of women, minorities and children in research

Other Review Considerations

- **Budget:** The proposed budget and the requested period of support in relation to the proposed research

- **Data Sharing Plan:** The data sharing plan or the rationale for not sharing research data

How will CTU Applications be Evaluated?

Questions?